

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 November 2001 (08.11.2001)

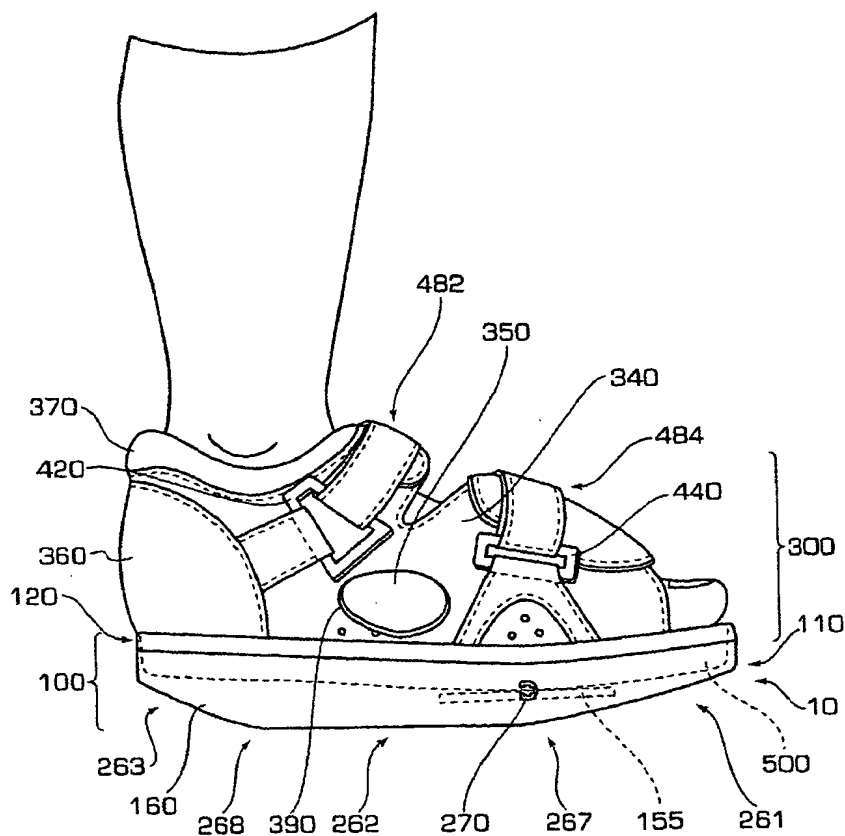
PCT

(10) International Publication Number
WO 01/82734 A1

- (51) International Patent Classification⁷: **A43B 13/18**, 13/38, 7/14
- (21) International Application Number: PCT/US01/11737
- (22) International Filing Date: 30 April 2001 (30.04.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/201,758 4 May 2000 (04.05.2000) US
- (71) Applicant (for all designated States except US): **DARCO INTERNATIONAL** [US/US]; P.O. Box 760, Huntington, WV 25712-0760 (US).
- (72) Inventor; and
(75) Inventor/Applicant (for US only): **DARBY, H., Darrel** [US/US]; c/o Darco International, Inc., P.O. Box 760, Huntington, WV 25712-0760 (US).
- (74) Agents: **HANNON, Brian, W. et al.**; Sughrue, Mion, Zinn, MacPeak & Seas, PLLC, Suite 800, 2100 Pennsylvania Avenue, N.W., Washington, DC 20037-3213 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

[Continued on next page]

(54) Title: HEALING SHOE OR SANDAL



(57) Abstract: A medical shoe (10) for use in supporting a patient's foot comprising an outsole (100), an upper assembly (300), a metatarsal shank (155), and an insole (120) with a plurality of different layers.

WO 01/82734 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

Description**HEALING SHOE OR SANDAL****BACKGROUND DESCRIPTION OF THE INVENTION**Field of the Invention

- [01] The present invention pertains to a shoe or sandal specifically designed to aid in the offloading, or reducing weight or pressure, from a specific area of the foot. The shoe or sandal, and specifically the insole and outer covering of the shoe upper, are designed to be altered by or under the direction of the health care provider to either offload weight from the bottom of the foot or to remove or reduce pressure from the sides, top or other specific areas of the foot.
- [02] The incidence of foot ulcers, infections and deformities of the feet has become an increasing problem as the life expectancy of patients with diabetes and other chronic diseases increase. The cost of treatment of these complex foot problems has escalated to the point that the Center for Disease Control and others in the health delivery system are placing a special emphasis on finding more effective ways of treating these problems. Patients with circulatory problems, diabetes, AIDS, arthritis neuropathies and other debilitating diseases experience complications that lead to increased deformities in the feet subjecting the deformed areas to increased pressures and friction. Spinal cord injuries and other injuries to the back and lower extremities may cause neuropathies that in turn produce deformities in the toes and feet with a loss of feeling causing more complications to develop. Chemically induced neuropathy from chemotherapy, alcohol, drug abuse, etc., may also lead to ulcerations and lesions of the feet that require special care. All of these problems are exacerbated by weight bearing pressure or friction from conventional shoes. Regardless of how aggressive the treatment plan, the use of expensive antibiotics, local wound care, surgery etc., healing is delayed and the lesions and infections reoccur unless effective measures are taken to redistribute weight reducing pressure and friction from the involved foot lesions.

Description of the Related Art

[03] Orthotics (orthopedic inserts) for supporting certain aspects of the human foot are well known in the field of podiatric medicine. However, orthotics can produce added pressure on the supported areas and cause rubbing which may lead to blistering or other ailments, complicating the above-described problems. Orthotics require additional space when used in conjunction with standard insoles and may even require extra space when comprised in a customized insole. Thus, when used in normal mass market shoes, orthotics can also cause rubbing on opposite surfaces of the foot, due to reduced clearance between foot and the shoe upper. Orthopedic shoes such as those manufactured by Markell ® and others provide extra depth to accommodate foot deformities and/or orthotics, but have an extremely awkward appearance, generally having a much higher profile (taller appearance) than normal mass-market shoes, and can be unstable when multiple inserts are used.

[04] The wound care shoe system is designed to produce a foot friendly environment where pressure and friction are reduced allowing healing to take place and to reduce the incidence of reoccurrence of a lesion. The invention provides an easy to use healing shoe or sandal and an effective method to offload weight from a particular area of the plantar aspect (bottom) of the human foot by using alterable insoles or insole layers of varying densities and degrees of firmness which fit into an area surrounded by a circumferential counter, in order to hold the insole layers in position. This creates a low profile more stable shoe than prior art extra depth shoes. The outer covering of the upper is also constructed of materials that can be cut out or heat molded or otherwise altered to reduce friction and/or pressure from the non-weight bearing areas of the foot.

SUMMARY OF THE INVENTION

[05] The above and other objects of the invention, which will become apparent hereinafter, are achieved by the provision of an adjustable sandal or shoe with the

upper constructed of a combination outer cover, preferably of leather, with an inner liner preferably of EVA or Plastizote, or similar material. This upper permits small portions of the outer cover over a lesion or bony prominence to be cut away leaving the underlying moldable liner of EVA for protection without destroying the integrity of the shoe. This removes the friction and pressure from the area over the lesion permitting faster healing. An out sole, including a base portion having a rocker bottom and a circumferential counter are molded in one piece providing a cavity with space for the various layers of insole material as well as stabilizing the insoles within the cavity of the outsole. The insoles are fabricated of soft, medium and firm density EVA or other suitable materials that mold to the foot. Certain sections of the insoles can be ground down or cut away, to redistribute weight away from a lesion or areas of excessive pressure. The insoles are either heat or pressure moldable. A fitting marker is also located on the medial side of the out sole in order to aid the health care provider in proper shoe fitting.

BRIEF DESCRIPTION OF THE DRAWINGS

[06] Fig. 1 is a top and front elevation of the wound care sandal or shoe forming a preferred embodiment.

[07] Fig. 2. is a medial side elevation of the wound care shoe illustrating a fitting marker molded on the side of the out sole, and an upper composed of an outer covering and a lining with the outer covering cut away to expose the lining and remove pressure from an ulcer or other lesion while the underlying soft lining remains in place to provide protection while reducing pressure over the lesion. Fig. 2 also illustrates a rocker bottom out sole which improves ambulation while reducing weight bearing pressure from the heel and forefoot as well as reducing friction within the shoe from foot movement, and a foam-padded collar designed to reduce pressure and provide comfortable fit around the heel and ankle.

- [08] Fig. 3 is a cut-away or cross section of the foot and healing shoe showing the circumferential counter extending upward from the sole, and four (4) layers of multi-density insoles, as well as the layer of polywood and a metatarsal shank.
- [09] Fig. 4 is a longitudinal cross section of the wound care shoe illustrating the insole layers, metatarsal shank within the outsole and circumferential counter.
- [10] Fig. 5A. is a cross section of a human foot illustrating the metatarsals and phalanges of the foot.
- [11] Fig. 5B. is a cross section of the shoe and foot at the metatarsal head level illustrating an altered insole to remove pressure from a plantar lesion of the foot.
- [12] Fig. 6. is a side elevation of the wound care shoe showing the opposite side of the wound care shoe from Fig. 2.
- [13] Fig. 7 illustrates the general shape of the out sole in a plantar aspect of the human foot, in conjunction with table 2.
- [14] Fig. 8 illustrates the arrangement of the insole layers of the wound care shoe for treating a specific type of ailment.
- [15] Fig. 9 illustrates the arrangement of the insole layers of the wound care shoe for treating an alternate specific type of ailment.
- [16] Fig. 10 illustrates a preferred cut out of at least one insole layer of the wound care shoe for treating a wound.
- [17] Fig. 11 illustrates the arrangement of the insole layers of the wound care shoe for treating another alternate type of ailment.
- [18] Fig. 12 illustrates the arrangement of the insole layers of the wound care shoe for treating yet another specific type of ailment.
- [19] Fig. 13 illustrates the arrangement of the insole layers of the wound care shoe for treating still another type of ailment.

DETAILED DESCRIPTION OF THE INVENTION

- [20] A sandal or shoe 10 for use by health care professionals in the treatment of infections, ulcerations, and other conditions of the foot, due to complications of diabetes or other medical conditions such as rheumatoid arthritis, vascular conditions,

neuropathy, or due to trauma of the feet from a variety of causes, in which it is desirable to redistribute weight away from the infected or traumatized area to be treated. The design (as shown in Fig. 2) of the sandal or shoe 10 includes a molded out sole 100, an upper portion 300, and an adjustable insole 500.

[21] The shoe is designed to accommodate the use of layers of various insole materials generally of a microcellular foam, but not limited to such, including without limitation Plastizote (Plastizote is a medically inert, high density polyethylene closed cell foam having excellent memory and impact absorption properties), Ethylene Vinyl Acetate (E V A), Poron (Poron is a impact absorbing open cell cellular urethane foam product), or similar material, to offload specific areas of the foot in order to promote healing of fractures, ulcers or infections when healing may be delayed by weight bearing pressure on the lesion.

[22] The molded out sole may be constructed from any suitable material including without limitation Ethylene Vinyl Acetate (E V A); polyurethane or other plastic or thermoplastic; rubber, including thermoplastic rubber (TPR), styrene butadiene rubber and natural rubber; or combination thereof. The out sole includes a base portion and a circumferential counter portion. The circumferential counter is molded as a part of the out sole extending completely around an upper portion of the circumference of the out sole. The circumferential counter extends upward from the upper surface of the base portion of the out sole, over an upper portion of the shoe from $\frac{1}{4}$ to 1 inch.

[23] The circumferential counter extends around the circumference of the top portion of the out sole and forms an opening, cavity, depression or pocket that allows the upper portion of the shoe to be conjoined with or counter sunk into the out sole. This permits extra depth in the upper portion of the shoe in which a variety of insole layers can be placed. The shoe, despite the extra depth, will have a lower profile than the prior art because the extra depth is within the out sole rather than the shoe upper. The cavity within the out sole of the shoe will provide a lower profile more like a conventional shoe while at the same time providing the extra room necessary to accommodate the multi-density insoles or insole layers.

[24] Various types and thickness of insole material such as EVA can be placed in the cavity portion of the out sole of the shoe and may be altered by either grinding or cutting away particular sections to remove weight or provide offloading of the specific area of the foot being treated. The cavity in the out sole permits the application of insole material below the level of the top of the circumferential counter thereby providing greater stability for the (human) foot and preventing the layered insole material from shifting as occurs in conventional shoes and particularly conventional extra depth shoes, if a layered insole is placed in a conventional extra depth shoe where the extra depth (and therefore the layered insole material) is above the out sole level.

[25] The upper surface of the base portion of the out sole (inside the cavity) has a small rectangular opening or trough to accommodate a plastic or metal shank (metatarsal shank). The metatarsal shank (155), as shown in Fig. 4, begins at a location corresponding approximately with the distal 1/3 of the metatarsals (710, as shown in Fig. 5) of a human foot (700) encased by the shoe or sandal as viewed from the plantar aspect (near the axial center of the outsole of the shoe), and extends distally (axially) across the metatarsal-phalangeal joints (phalanges (750) shown in Fig. 5) of the foot (700) as viewed from the plantar aspect. The metatarsal shank reduces motion in the shoe and in the corresponding portion of the foot, as well as adds strength to the out sole.

[26] With reference to Fig. 1, the upper 300 of the shoe 10 is closed around the human foot 700 (as shown in Fig. 5) by overlapping inner 310 and outer 320 flaps secured by any of fastening means including but not limited to: buttons and corresponding button holes, snaps, eyelet holes with interconnecting laces, or patches of a hook and loop material (e.g., VELCO®). An additional and preferred alternative is interconnection of the overlapping inner 310 and outer 320 flaps using hook and loop straps (generally, 380). One strap closes in front of the ankle (a first or ankle strap 482) to lock the heel in position to reduce slipping of the heel in the shoe. The

second (forefoot) strap 484 fastens over the forefoot to hold this portion of the foot in place. Each flap includes a first (ankle) ring 420 corresponding to the ankle strap 482 and a second (forefoot) ring 440 corresponding with the forefoot strap 484. The ankle 420 and forefoot 440 rings are positioned directly across (transversely) from one another and the respective strap (482 or 484) is threaded through the respective pair of rings (420 or 440) and secured, thereby securing the inner 310 and outer 320 flaps in place by applied pressure and tension (between the ring pairs). Additionally, the straps 380 may be stitched at intervals 484, to permit shortening of the straps as edema subsides or the bulk of bandages are reduced. The straps are cut in front of the appropriate stitch line 488 to prevent fraying of the straps.

[27] As illustrated in Fig. 2, the shoe upper 300 is constructed of an outer covering 340 of leather, canvas, nylon mesh or other suitable material with an inner lining 350 of EVA or soft foam material that can be easily separated from the outer covering. The inner lining 350 reduces friction against the non-weight bearing surfaces of the foot while providing increased comfort. This construction allows the removal of a specific section of the outer covering (as shown at 390 in Fig. 2) over a pressure point or lesion leaving the soft, heat or pressure moldable inner lining 350 (EVA), in place over the ulcer or prominence for protection. There is also a foam-padded collar 370 around the heel and ankle portion (heel portion or heel counter 360) of the shoe or sandal 10, to prevent pressure from the outer covering 340 material and reduce heel slippage. To assist the health care provider in proper fitting of the shoes a fitting marker 270 is molded into the medial side of the out sole 100. The end of the first metatarsal 710 generally should extend slightly in front of the fitting marker 270 to reduce pressure under the metatarsal heads 720 (as shown in Fig. 5) and permit the rocker bottom out sole 160 (as discussed below) to perform properly.

[28] With reference to Fig. 3, the molded out sole 100 of the shoe or sandal 10 is designed with a circumferential counter 120 that extends $\frac{1}{4}$ to 1 inch onto the shoe upper 300 above the upper surface 130 of a base portion 110 of the outsole 100. Imbedded in the base portion 110 of the rocker bottom out sole 100 is the metatarsal

shank 155, constructed of metal, plastic or other suitable material that begins near the distal 1/3 of the metatarsals (710, as shown in Fig. 5) extending across the metatarsal-phalangeal joints to control motion in that portion of the foot. This out sole 100 and the circumferential counter 120, are molded in one piece and designed to add stability to the foot while providing space for the insole 500 including insole layers (generally, 520) of insole material (individually 600, 620, 640, 660), within the out sole cavity 140 to prevent shifting of the insole layers 520 and permit offloading of specific areas of the foot.

- [29] The insole layers 600, 620, 640 and 660 are constructed of Ethyl Vinyl Acetate (EVA) or other suitable material of varying densities. The cavity (pocket) 140 formed by the circumferential counter 120 also presents a lower profile in that the insole layers 520 are confined within the molded out sole 100 below the level of the upper portion of the shoe rather than in the shoe upper itself. The poly-wood layer 680, forming the foundation of the insole 500, is about 2mm thick. The durometer (hardness) or relative density of the insole layers 600, 620, 640 and 660 are preferably within 5 degrees of the following example of the preferred embodiment but are not in anyway limited thereto.

Table 1

<u>Insoles Layer</u>	<u>Durometer</u>	<u>Thickness</u>	<u>Material</u>
600	26	1/4 in.	soft EVA or Plastizote
620	29	1/8 in.	high-density foam/soft Poron
640	42	1/4 in.	medium-density foam/ EVA or Plastizote
660	50	1/4 in.	firm-density foam/ EVA or Plastizote

- [30] With reference to Fig. 4, the layers 520 of insole material 600, 620, 640 and 660 and the inventive out sole 100 provide the extra height (depth) necessary (as if these components were actually a part of the out sole) to create a rocker bottom sole.

The rocker bottom 160 of the out sole 100 permits easy ambulation while at the same time allowing the patient to stand on the flat stable mid section 262 of the rocker bottom 160 of the out sole 100. The rocker apex 267 of the rocker bottom 160 of the out sole 100 is located at (just below) the fitting marker 270 or just proximal to the metatarsal heads (720, see Fig. 5 A & B) to reduce pressure from the metatarsal heads 720 and then tapers off toward the toe of the out sole in the toe section 261. The heel section 263 of the rocker bottom 160 of the out sole 100 is tapered at an oblique angle from mid-section 262 to the rear of the rocker bottom 160 of the out sole 100 in a manner to cause heel strike about mid-heel at the oblique angle 268 between the heel section 263 and mid section 262. The rocker bottom 160 combined with the metal or plastic metatarsal shank 155, allows the patient to ambulate comfortably while reducing motion of the foot thereby reducing the friction caused by the foot movement within the shoe.

[31] Referring now to Fig. 5 A & B, the shoe upper 300 having an inner lining 350 and an outer covering 340, as well as the insole layers 520 (600, 620, 640 and 660) of EVA, Poron and or other suitable material are designed to be altered as shown at 550 (see Fig. 2 at 390 for alteration of the upper), by or under the direction of the health care provider to offload weight from a specific area 770 of the foot. While the manner in which the insoles or shoe need to be altered is a clinical judgment for the health care provider, a method for altering the shoe is described hereinafter.

[32] Non-weight bearing ulcers generally occur over the posterior, medial or lateral aspect (on the top (dorsal) portion of the foot as opposed to the plantar aspect. For non-weight bearing ulcerations, regardless of grade (severity), the external cover of the shoe only is removed (see Fig. 2, element 390) leaving the soft inner lining intact to protect the lesion being treated and reduce the occurrence of window edema. Air holes may be added to the outer covering 340 in order to facilitate outer covering removal in those areas where ulcers are most likely to occur. Where such air holes are provided, the health care professional optimally should pass a small, blunt object (e.g., a large paperclip) from one air hole to the adjacent air hole in the outer covering,

being careful not to penetrate the inner lining in order to remove a particular region of the outer covering without damaging the inner lining. Alternately, using a sharp instrument, the health care professional should cut away the portion of the outer covering surrounding (directly above) the lesion to be treated or between the air holes nearest the lesion in order to remove the required amount of outer covering. The initial cut should be below the level of the top of the area being removed (dorsally). A flat instrument or tongue depressor may then be inserted between the covering and the lining to prevent accidental cutting or damage to the lining when the covering is cut away. Insole layers 520 should optimally be arranged as indicated by Fig. 8 when no open ulcers are present. Should the ulcer or inflammation extend to the plantar surface of the foot, the insoles should be altered in the same manner as described below for the treatment of plantar (weight-bearing) ulcers.

[33] When treatment of weight-bearing ulcers of grade 0 and 1 on the Wagner Scale on the plantar surface of the foot is required, the insole layers 520 optimally should be placed in the order as indicated in Fig. 9. Using a sharp instrument such as a scalpel or utility knife, the health care professional should cut away an oval area (area to be removed 550) of the medium density insole layer 640 directly under the ulcer as shown in Fig. 5 B and Fig. 9. The health care professional should skive the edges to an angle of approximately 30° so that the opening farther away from the foot is slightly larger than the opening nearer the plantar surface of the foot. The oval relief area should be approximately 0.5 cm larger than the ulcer and extend distally 1.25 cm as shown in Fig 10. A hard, smooth-cutting surface should be used to obtain more accurate and safe cutting results. After the wound has closed, the insole layers should be rearranged as indicated in Fig 11. The shoe can then be used as a household ambulation slipper.

[34] When treatment of weight-bearing ulcers of grade 2 and above on the Wagner Scale on the plantar surface of the foot is required, the insole layers 520 optimally should be placed in the order as indicated in Fig. 12. Using a sharp instrument such as a scalpel or utility knife, the health care professional should cut away an oval area

550 of the medium density insole layer 640 and the firm density insole layer 660 directly under the ulcer as shown in Figs. 5 (showing only the removal of medium density insole layer 640) and 12. The oval relief area should be approximately 0.5 cm larger than the ulcer and extend distally 1.25 cm as described previously with respect to Fig. 10. When the oval area is cut away from the medium density insole layer, the firm density insole layer or both, the opening in the insole should be slightly larger on the bottom (further from the wound) than the top (nearer the wound) in order to minimize pressure and shear to the ulcer margin. After the wound has closed, the insole layers should be rearranged as indicated in Fig. 13. The shoe can then be used as a household ambulation slipper.

[35] Proper fitting of the Wound Care shoe is essential for optimal results. To this end, the fitting marker 270 as shown in Fig 2 is molded into the out sole 100 to assist in proper fitting. The head of the first metatarsal (720 in Fig. 5 A & B) should be positioned such that it is slightly in front of the fitting marker 270 to ensure that the other metatarsal heads are just in front of the high point (rocker apex 267) of the rocker bottom 160 of the out sole 100 to reduce the weight-bearing load on the metatarsal heads and forefoot.

[36] Additionally, a variety of out sole dimensions are contemplated in order to accommodate a wide variety of foot shapes and sizes, as illustrated in Fig. 7 and described in table 2, below. All dimensions are in centimeters (cm).

Table 2

	<u>Out Sole Dimensions</u>		
	A	B	C
Small	26.00	9.25	6.25
Medium	27.00	10.25	7.00
Large	28.25	10.50	7.50
X-Large	30.50	11.00	7.50
XX-Large	32.00	11.25	7.75

- [37] While the present invention and method for using same has been described using specific terms and preferred embodiments, such description is for illustrative purposes only, and it is understood that changes and variations may be made by one skilled in the art without deviating from the broad principles and teachings of the present invention which shall be limited solely by the scope of the claims appended hereto.

Claims

What is claimed is:

1. A medical shoe for use in supporting a patient's foot comprising:
 - an out sole;
 - an upper assembly secured to and partially surrounded by the out sole;
 - an insole assembly substantially enclosed by the out sole and the upper assembly;
 - the out sole having a base portion generally corresponding with the plantar aspect of a human foot and of varying thickness and having a substantially rectangular opening in a top surface thereof adapted for accommodating a metatarsal shank;
 - the out sole having a circumferential counter portion extending upward circumferentially from the top surface of the base portion of the out sole around the base portion of the out sole thereby providing a cavity in the out sole;
 - the upper assembly including a heel portion, an intermediate portion and a toe portion, the heel section and intermediate section integrally connected;
 - the upper assembly adapted to surround at least the heel, sides and dorsal portions of the human foot;
 - the upper assembly attached to the top surface of the base portion of the out sole and the circumferential counter of the out sole, and extending in a dorsal direction from the top surface of the base portion of the out sole along the circumferential counter;

the insole assembly having a plurality of insole layers disposed in the out sole cavity and surrounded by the upper assembly and the out sole circumferential counter;

the plurality of insole layers provided to include at least one of a plurality of differing insole layer thickness, materials, hardnesses and densities.

2. The medical shoe as claimed in claim 1, wherein the insole assembly includes at least a first and a second insole layer wherein the first and second layers are an Ethyl Vinyl Acetate (EVA) material, and the second layer has a durometer less than the first layer.

3. The medical shoe as claimed in claim 2, wherein the insole assembly includes the first and second insole layers, and a third and a fourth insole layer wherein the third layer is a Poron material with a durometer less than the second layer and the fourth layer is an EVA material with a durometer less than the third layer; and

wherein the first, second, third, and fourth layers may be assembled in any order as determined by a health care professional.

4. The medical shoe as claimed in claim 1, wherein the opening for the metatarsal shank is centered laterally and extends distally from a location substantially corresponding to the distal 1/3 of the metatarsals in a plantar aspect of a corresponding foot to be supported by the medical shoe, and
wherein the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material.

5. The medical shoe as claimed in claim 2, wherein the opening for the metatarsal shank is centered laterally and extends distally from a location substantially corresponding to the distal 1/3 of the metatarsals in a plantar aspect of a corresponding foot to be supported by the medical shoe; and

wherein the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material.

6. The medical shoe as claimed in claim 3, wherein the opening for the metatarsal shank is centered laterally and extends distally from a location substantially corresponding to the distal 1/3 of the metatarsals in a plantar aspect of a corresponding foot to be supported by the medical shoe; and wherein the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material.

7. The medical shoe as claimed in claim 4, wherein a bottom surface of the base portion of the out sole has a unique rocker shape, a rocker bottom, adapted to permit easy ambulation while also providing a stable platform for standing;

the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section.

8. The medical shoe as claimed in claim 5, wherein a bottom surface of the base portion of the out sole has a unique rocker shape, a rocker bottom, adapted to permit easy ambulation while also providing a stable platform for standing;

the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section.

9. The medical shoe as claimed in claim 6, wherein a bottom surface of the base portion of the out sole has a unique rocker shape, a rocker bottom, adapted to permit easy ambulation while also providing a stable platform for standing;

the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section.

10. The medical shoe as claimed in claim 7, wherein the apex of the rocker bottom which is adapted to form the oblique angle between the mid-section and the tapered toe section is located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section is located just below mid-heel, and the taper of the heel section is adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section.

11. The medical shoe as claimed in claim 8, wherein the apex of the rocker bottom which is adapted to form the oblique angle between the mid-section and the tapered toe section is located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section is located just below mid-heel, and the taper of the heel section is adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section.

12. The medical shoe as claimed in claim 9, wherein the apex of the rocker bottom which is adapted to form the oblique angle between the mid-section and the tapered toe section is located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section is located just below mid-heel, and the taper of the heel section is adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section.

13. The medical shoe as claimed in claim 3, wherein the toe portion of the upper assembly is comprised of one of an open toe portion and a closed toe portion, the closed toe portion adapted to surround the metatarsal and

phalangel portions of the human foot and attached to the base portion and circumferential counter of the out sole in the same manner as the heel portion and intermediate portion of the upper assembly.

14. The medical shoe as claimed in claim 6, wherein the toe portion of the upper assembly is comprised of one of an open toe portion and a closed toe portion, the closed toe portion adapted to surround the metatarsal and phalangel portions of the human foot and attached to the base portion and circumferential counter of the out sole in the same manner as the heel portion and intermediate portion of the upper assembly.

15. The medical shoe as claimed in claim 12, wherein the toe portion of the upper assembly is comprised of one of an open toe portion and a closed toe portion, the closed toe portion adapted to surround the metatarsal and phalangel portions of the human foot and attached to the base portion and circumferential counter of the out sole in the same manner as the heel portion and intermediate portion of the upper assembly.

16. The medical shoe as claimed in claim 13, wherein the intermediate portion of the upper assembly includes inner and outer intermediate flaps adapted to cover the dorsal portion of the human foot, and connection means for interconnecting the inner and outer intermediate flaps.

17. The medical shoe as claimed in claim 14, wherein the intermediate portion of the upper assembly includes inner and outer intermediate flaps adapted to cover the dorsal portion of the human foot, and connection means for interconnecting the inner and outer intermediate flaps.

18. The medical shoe as claimed in claim 15, wherein the intermediate portion of the upper assembly includes inner and outer intermediate flaps adapted to cover the dorsal portion of the human foot, and connection means for interconnecting the inner and outer intermediate flaps.

19. The medical shoe as claimed in claim 16, wherein the connection means is comprised of one of buttons and button holes, snaps, hook and loop fastener patches, and holes with corresponding laces.

20. The medical shoe as claimed in claim 17, wherein the connection means is comprised of one of buttons and button holes, snaps, hook and loop fastener patches, and holes with corresponding laces.

21. The medical shoe as claimed in claim 18, wherein the connection means is comprised of one of buttons and button holes, snaps, hook and loop fastener patches, and holes with corresponding laces.

22. The medical shoe as claimed in claim 19, wherein the connection means is comprised of straps included a first and a second strap, each of the inner and outer flaps including a first and a second ring attached to the respective flap with each first and second ring aligned transversely with one another, and the first and second straps are provided threaded between each of the first and second rings respectively to interconnect the flaps by a pressing and a tension force;

the straps comprising one of fastening mechanisms of hook and loop fasteners, button fasteners and snap fasteners.

23. The medical shoe as claimed in claim 20, wherein the connection means is comprised of straps included a first and a second strap, each of the inner and outer flaps including a first and a second ring attached to the respective flap with each first and second ring aligned transversely with one another, and the first and second straps are provided threaded between each of the first and second rings respectively to interconnect the flaps by a pressing and a tension force;

the straps comprising one of fastening mechanisms of hook and loop fasteners, button fasteners and snap fasteners.

24. The medical shoe as claimed in claim 21, wherein the connection means is comprised of straps included a first and a second strap, each of the inner and outer flaps including a first and a second ring attached to the respective flap with each first and second ring aligned transversely with one another, and the first and second straps are provided threaded between each of the first and second rings respectively to interconnect the flaps by a pressing and a tension force;

the straps comprising one of fastening mechanisms of hook and loop fasteners, button fasteners and snap fasteners.

25. A medical shoe for use in supporting a patient's foot comprising:

an out sole;

an upper assembly secured to and partially surrounded by the out sole;

an insole assembly substantially enclosed by the out sole and the upper assembly;

the out sole having a base portion generally corresponding with the plantar aspect of a human foot and of varying thickness and having a substantially rectangular opening in a top surface of the base portion thereof adapted for accommodating a metatarsal shank;

the opening for the metatarsal shank centered laterally and extending distally from a location substantially corresponding to the distal 1/3 in a plantar aspect of the metatarsals of the foot to be supported by the medical shoe, and the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material;

the out sole having a circumferential counter portion extending upward circumferentially from the top surface of the base portion thereof around the base portion of the out sole thereby providing a cavity in the out sole;

the upper assembly adapted to surround at least the heel, sides and dorsal portions of the human foot, the upper assembly including a heel portion, an intermediate portion and a toe portion, the heel portion and intermediate portion integrally connected, the toe portion comprised of one of an upper toe portion and a closed toe portion, the closed toe portion adapted to surround the metatarsal and phalangeal portions of the human;

the upper assembly attached to the top surface of the base portion of the out sole and the circumferential counter of the out sole, and extending in a dorsal direction from the top surface of the base portion of the out sole along the circumferential counter;

the insole assembly having a plurality of insole layers disposed in the out sole cavity and surrounded by the upper assembly and the out sole circumferential counter;

the plurality of insole layers provided to include a first insole layer, a second insole layer a third insole layer and a fourth insole layer wherein the first and second layers are an Ethyl Vinyl Acetate (EVA) material and the second layer has a durometer less than the first layer, the third layer is a Poron material with a durometer less than the second layer, and the fourth layer is an EVA material with a durometer less than the third layer, and the first, second, third, and fourth layers may be assembled in any order as determined by a health care provider;

the base portion of the out sole having a rocker bottom surface, adapted to permit easy ambulation while also providing a stable platform for standing, the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section, the apex of the rocker bottom adapted to form the oblique angle between the mid-section and the tapered toe section and located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section located just below

mid-heel, the taper of the heel section adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section,

the intermediate portion of the upper assembly including inner and outer intermediate flaps adapted to cover the dorsal portion of the human foot, and a first and second strap adapted for using a hook and loop fastening mechanism for interconnecting the inner and outer intermediate flaps, each of the inner and outer flaps including a first and a second ring attached to the respective flap with each first and second ring aligned transversely with one another, and the first and second straps are provided threaded between each of the first and second rings respectively to interconnect the flaps by a pressing and a tension force.

26. A method for using the medical shoe of claim 25, comprising the step of fitting the shoe such that the head of the first metatarsal of the human foot is positioned slightly in front of the fitting marker of the out sole to ensure that the other metatarsal heads of the human foot are just in front of the rocker apex of the rocker bottom of the out sole to reduce a weight-bearing load on the metatarsal heads and forefoot.

27. A method for using the medical shoe of claim 25, comprising the step of treating a non-weight bearing area by removing a portion of the external cover of the upper portion of the shoe surrounding and directly above the area to be treated without removing or damaging the soft inner lining so that the area being treated is protected.

28. A method for using the medical shoe of claim 26, further comprising the step of treating a non-weight bearing area by removing a portion of the external cover of the upper portion of the shoe surrounding and directly above the area to be treated without removing or damaging the soft inner lining so that the area being treated is protected.

29. A method for using the medical shoe of claim 25, comprising the step of treating a weight bearing area by removing an oval area of at least one of the insole layers directly under the area to be treated, wherein the edges of oval area are skived to an angle of approximately 30° so that the opening farther away from the area to be treated is slightly larger than the opening nearer the area to be treated, and the upper limit of the oval area is approximately 0.5 cm larger than the area to be treated and extends distally 1.25 cm from the area to be treated.

30. A method for using the medical shoe of claim 26, further comprising the step of treating a weight bearing area by removing an oval area of at least one of the insole layers directly under the area to be treated, wherein the edges of oval area are skived to an angle of approximately 30° so that the opening farther away from the area to be treated is slightly larger than the opening nearer the area to be treated, and the upper limit of the oval area is approximately 0.5 cm larger than the area to be treated and extends distally 1.25 cm from the area to be treated.

31. An insole assembly of a healing shoe having an upper assembly, an out sole assembly with a cavity therein, and an out sole circumferential counter, comprising:

a plurality of separably removable insole layers disposed in the out sole cavity;

the separably removable insole layers surrounded by the upper assembly and the out sole circumferential counter integrally attached to the out sole assembly and the upper assembly, the insole assembly adaptable for treating a weight bearing area of a human foot by removing an oval area of at least one of the insole layers directly under the area to be treated;

the plurality of separably removable insole layers provided to include at least one of a plurality of differing insole layer thickness, materials, hardnesses and densities.

32. The insole assembly of claim 31, wherein the edges of the oval area are skived such that the opening farther away from the area to be treated is slightly larger than the opening nearer the area to be treated.

33. A method for using the medical shoe of claim 32, comprising the step of fitting the healing shoe such that a head of a first metatarsal of a human foot is positioned slightly in front of a fitting marker provided on the surface of the out sole assembly to ensure that other metatarsal heads of the human foot are just in front of a rocker apex of a rocker bottom of the out sole assembly to reduce a weight-bearing load on the metatarsal heads and forefoot.

34. A method for using the medical shoe of claim 32, comprising the step of treating the weight bearing area by removing an oval area of at least one of the insole layers directly under the area to be treated, wherein the edges of oval area are skived to an angle of approximately 30° so that the opening farther away from the area to be treated is slightly larger than the opening nearer the area to be treated, and the upper limit of the oval area is approximately 0.5 cm larger than the area to be treated and extends distally 1.25 cm from the area to be treated.

35. A healing shoe for use in supporting a patient's foot comprising:

an out sole;

a circumferential counter portion attached to and extending upward circumferentially from the out sole;

a fitting marker provided on the side surface of the out sole for fitting of the healing shoe to a human foot.

36. The healing shoe of claim 35, wherein the fitting marker is provided on the medial side surface of the out sole approximately $1/3$ the longitudinal distance between a front surface of a tapered toe section of the shoe and rear surface of a tapered heel section of the shoe corresponding with an apex of a bottom surface of the of the out sole between a flat mid-section of the bottom surface and the tapered toe section in upwardly and forwardly oblique relation the flat mid-section, the fitting marker is provided for longitudinal positioning of a metatarsal-phalangel joint of the human foot within the healing shoe.

37. A method for using the medical shoe of claim 35, comprising the step of fitting the healing shoe such that a head of a first metatarsal of a human foot is positioned slightly in front of the fitting marker provided on the surface of the out sole to ensure that other metatarsal heads of the human foot are just in front of a rocker apex of a rocker bottom of the out sole assembly to reduce a weight-bearing load on the metatarsal heads and a forefoot.

38. A healing shoe having an upper assembly, an out sole assembly with a cavity therein, and an out sole circumferential counter, comprising:

an insole assembly disposed in the out sole cavity having a plurality of distinct insole layers;

the insole assembly surrounded by the upper assembly and the out sole circumferential counter integrally attached to the out sole assembly and the upper assembly;

each of the plurality of insole layers including at least one of a plurality of differing insole layer thickness, materials, hardnesses and densities; and

a fitting marker provided on the surface of the out sole assembly.

39. A method for using the healing shoe of claim 35, comprising the step of fitting the healing shoe such that a head of a first metatarsal of a human foot is positioned slightly in front of the fitting marker provided on the surface of the out sole assembly to ensure that other metatarsal heads of the human foot are just in front of a rocker apex of a rocker bottom of the out sole assembly to reduce a weight-bearing load on the metatarsal heads and forefoot.

40. A method for using the medical shoe of claim 36, wherein at least one additional insole layer may be added in the vicinity of an area of the human foot to be treated, the at least one additional insole layer having at least one of an insole layer thickness, material, hardness and density different from the plurality of insole layers of the insole assembly.

FIG. 1

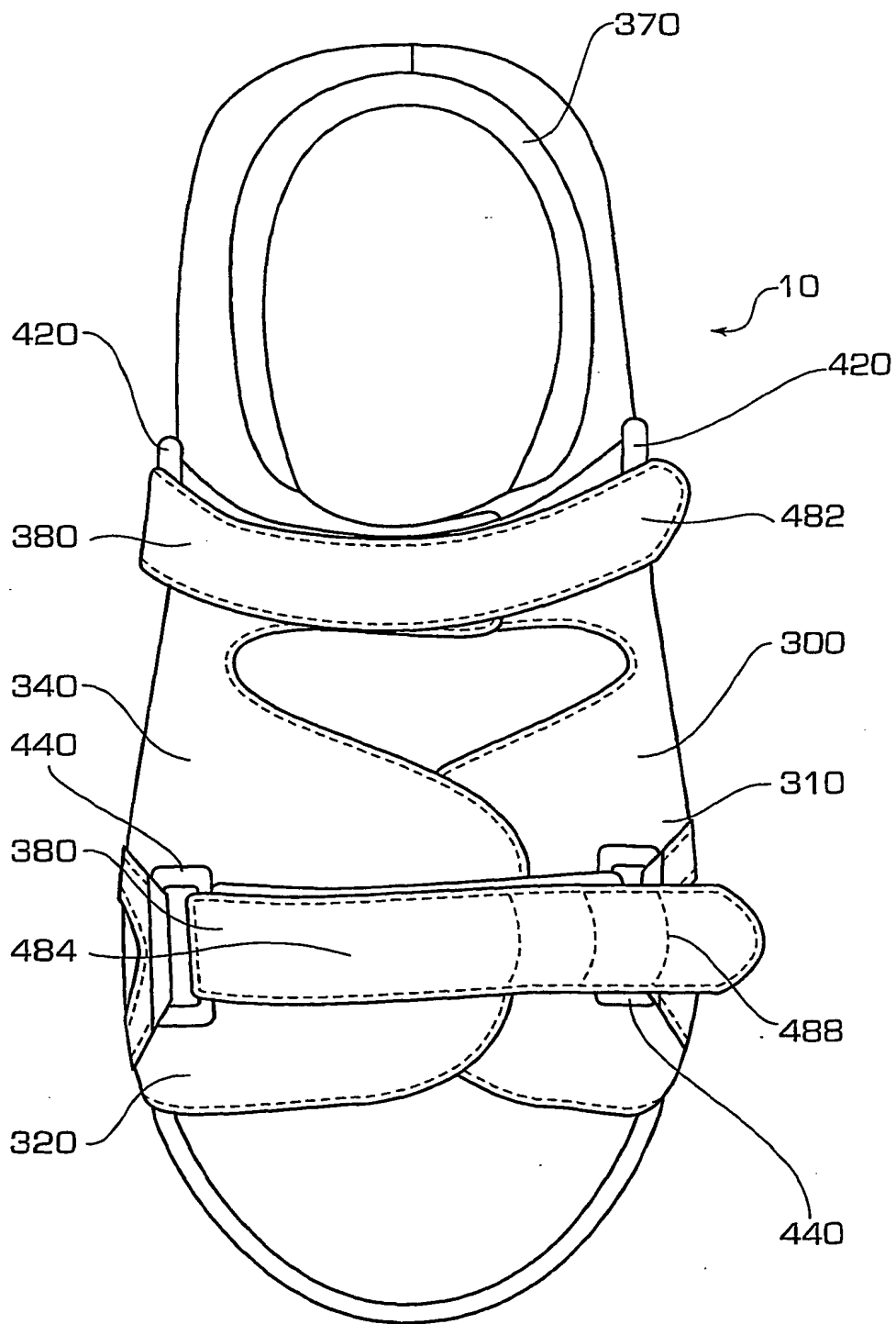


FIG. 2

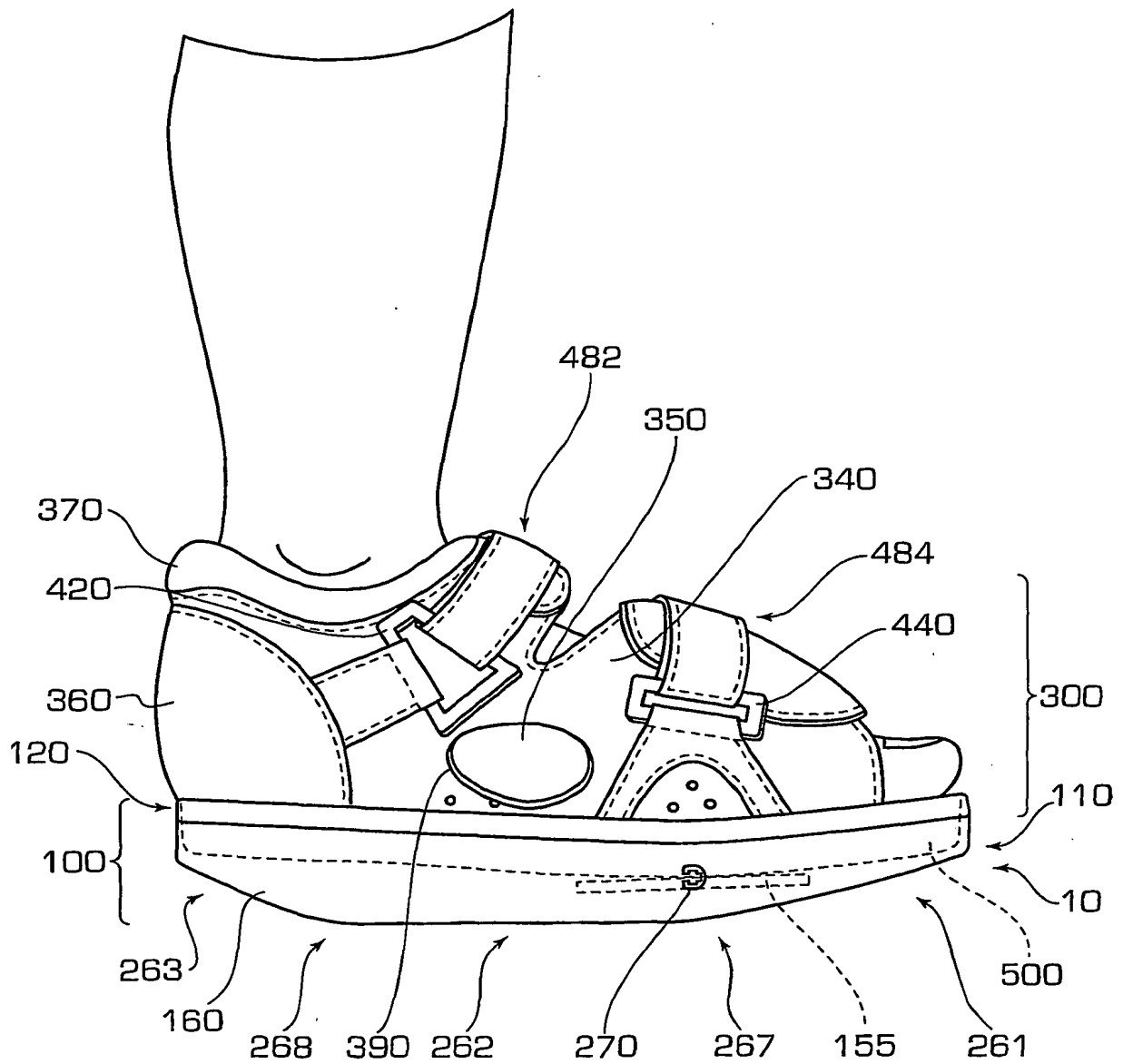


FIG. 3

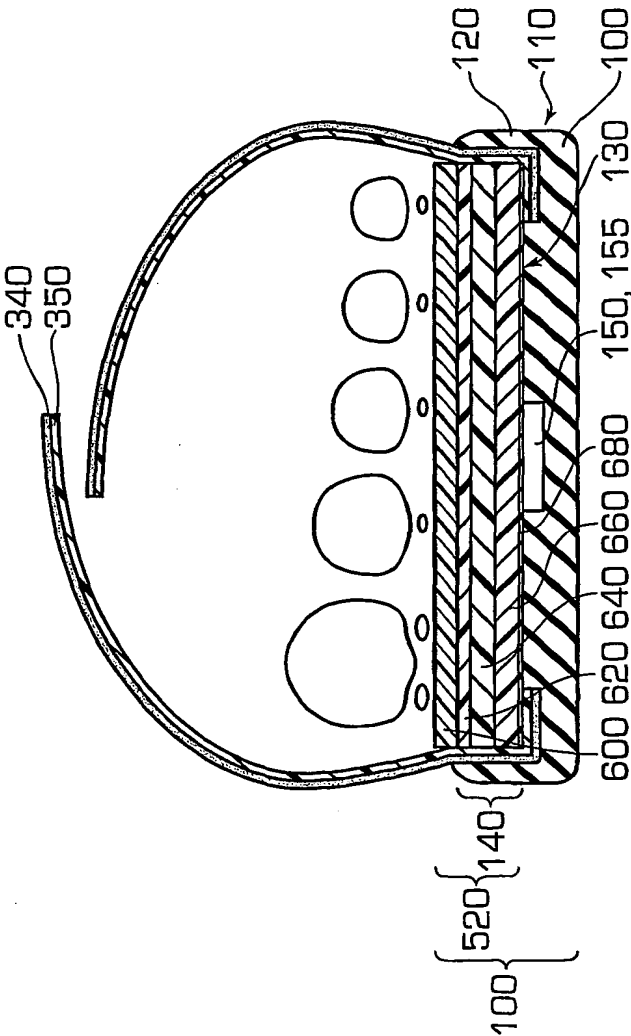


FIG. 4

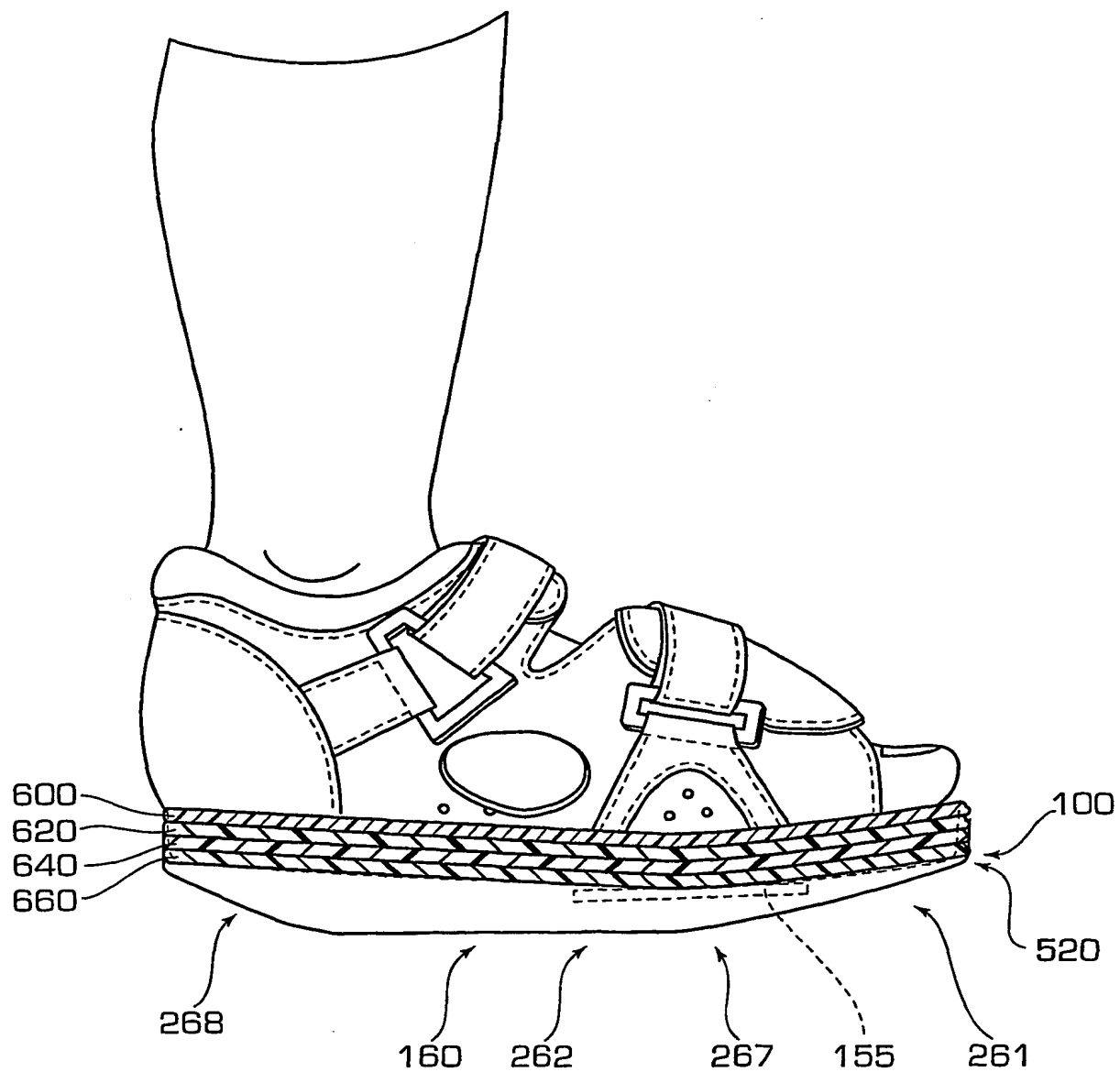


FIG. 5A

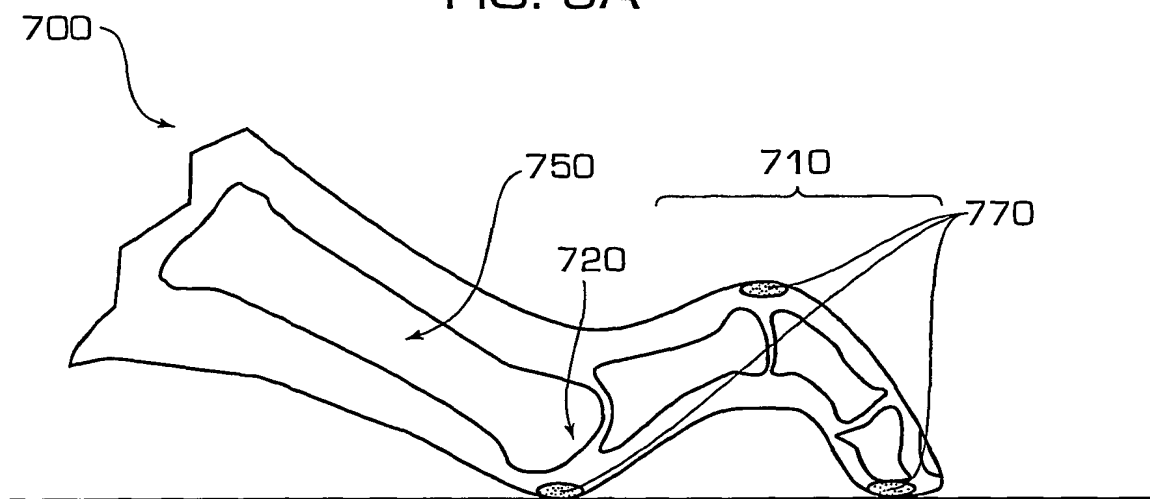


FIG. 5B

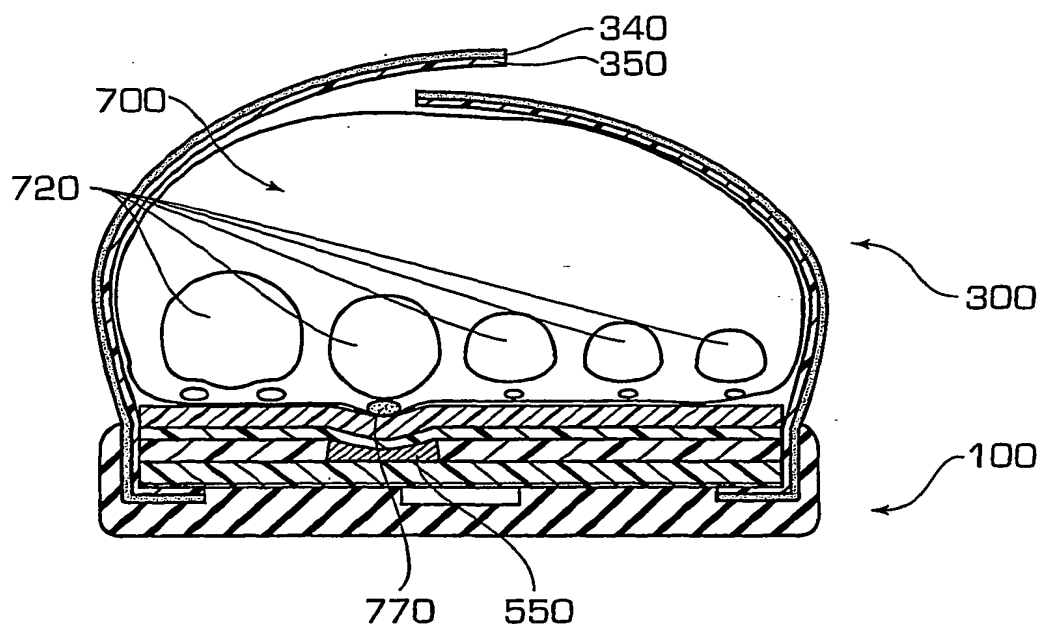


FIG. 6

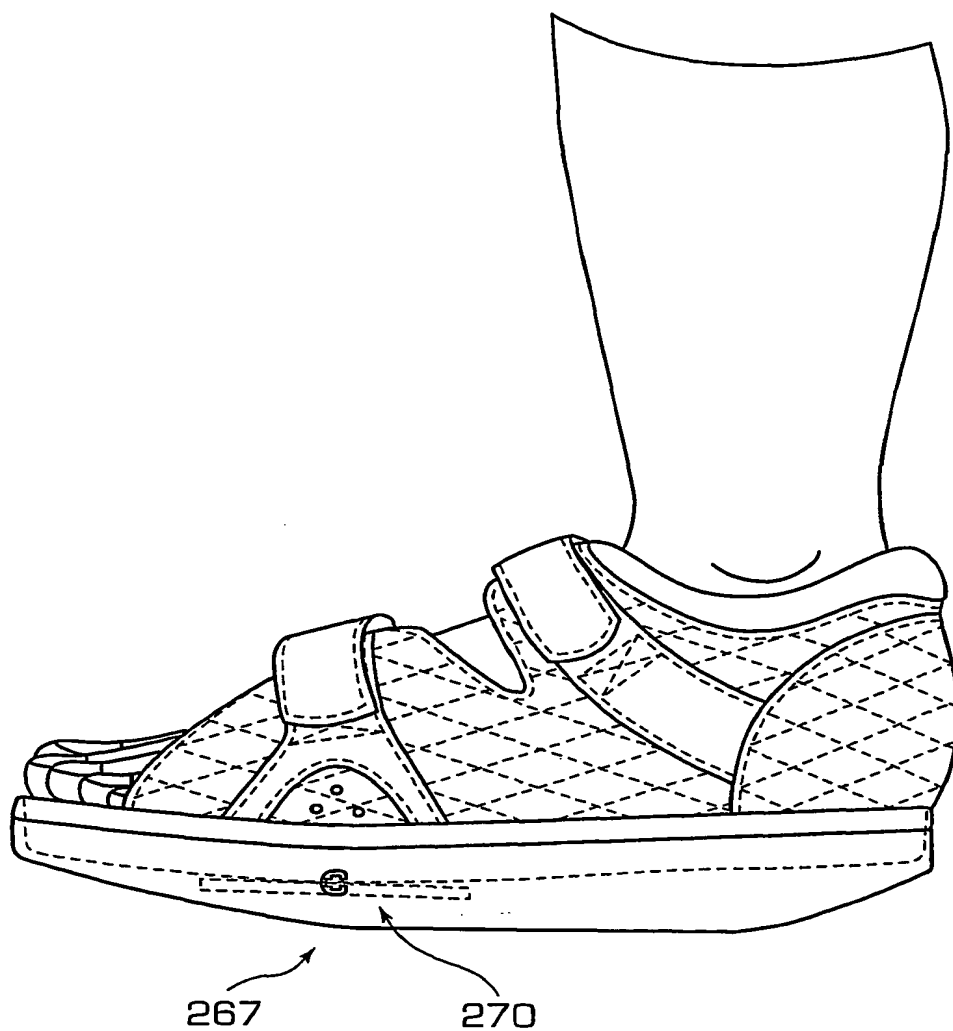


FIG. 7

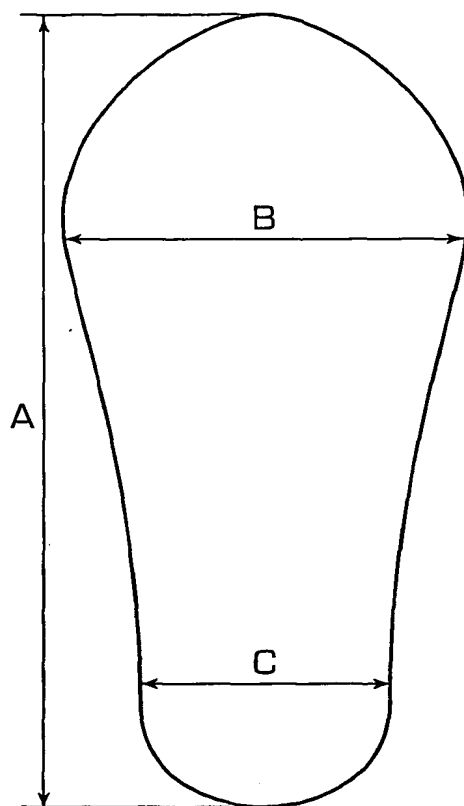


FIG. 10

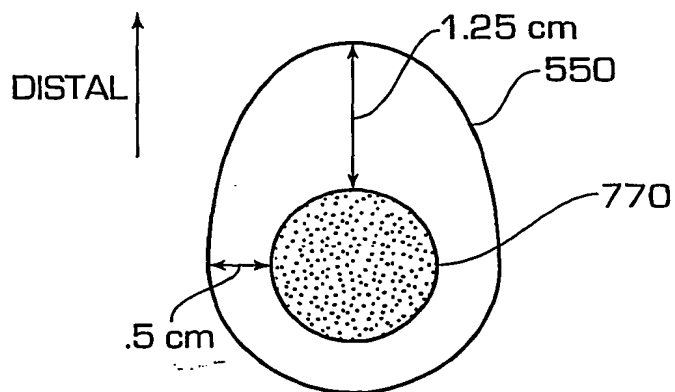


FIG. 8

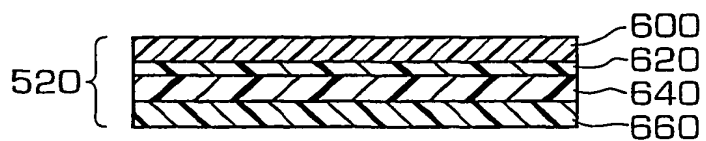


FIG. 9

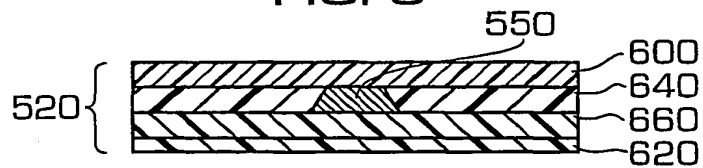


FIG. 11

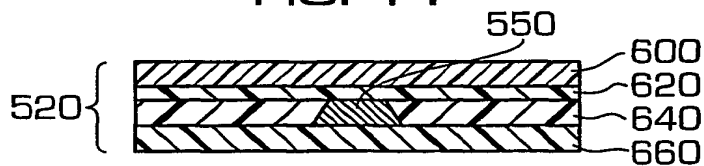


FIG. 12

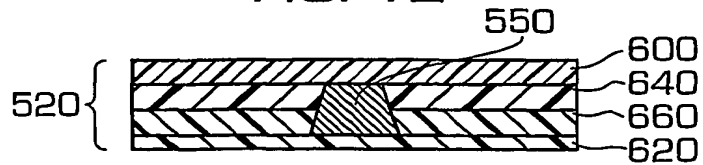
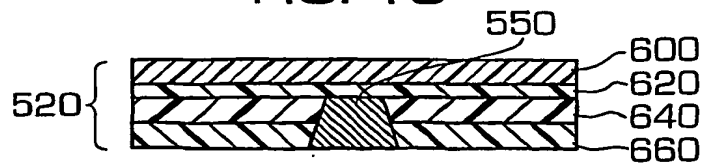


FIG. 13



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/11737

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A43B 13/18, 13/38, 7/14

US CL : 36/ 110, 88, 44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 36/ 110, 88, 44, 95, 45, 100, 101, 93

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,329,705 A (GRIM ET AL) 19 July 1994, see whole reference.	31, 35-37
---		-----
Y		1-30, 32-34, and 38-40
Y	US, 5,491,909 A (DARBY) 20 February 1996, see whole reference.	1-30, and 35-40
Y	US 2,389,032 A (DONNELLY) 13 November 1945, see whole reference.	27 and 28
X	US 4,793,078 A (ANDREWS) 27 December 1988, see whole reference.	31
---		-----
Y		32 and 33
Y	US 5,452,527 A (GAYLORD) 26 September 1995, see whole reference.	22-24

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

02 JULY 2001

Date of mailing of the international search report

27 JUL 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MARIE PATTERSON

Telephone No. (703) 308-0069

Sheila Vanev
Paralegal Specialist
 Technology Center 3700



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 370 133 A (DARBY H DARREL ET AL) 6 December 1994 (1994-12-06)	31,32	A61F5/01 A43B7/28 A43B13/12
Y	* column 4, line 39-54 - column 8, line 53-65 *	1,25, 33-40	
Y	US 5 491 909 A (DARBY H DARREL) 20 February 1996 (1996-02-20) * column 3, line 32-35; figures *	1,25	
Y	US 4 567 678 A (MORGAN R DEAN ET AL) 4 February 1986 (1986-02-04) * column 2, line 55-57; figures 1,6,7 * * column 3, line 28 * * column 4, line 63 * * column 8, line 34 *	33-40	
X	US 5 329 705 A (O'DONNELL KEVIN R ET AL) 19 July 1994 (1994-07-19)	31,32	
Y	* column 4, line 22 - column 5, line 30; figures 2,3,5 *	25,33, 34,38-40	
X	US 4 793 078 A (ANDREWS ANTHONY C) 27 December 1988 (1988-12-27) * the whole document *	31,32	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61F A43B
A	US 2 389 032 A (DONNELLY FRANK P) 13 November 1945 (1945-11-13) * the whole document *	27,28	
A	US 5 452 527 A (GAYLORD JR JOHN F) 26 September 1995 (1995-09-26) * the whole document *	22-24	
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search MUNICH		Date of completion of the search 16 May 2003	Examiner Herry, M
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 93 4867

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-05-2003

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5370133	A	06-12-1994	NONE		
US 5491909	A	20-02-1996	NONE		
US 4567678	A	04-02-1986	US	4414759 A	15-11-1983
US 5329705	A	19-07-1994	AU	6245194 A	14-09-1994
			CA	2155346 A1	01-09-1994
			DE	69430733 D1	11-07-2002
			DE	69430733 T2	27-03-2003
			EP	0686005 A1	13-12-1995
			ES	2177576 T3	16-12-2002
			WO	9418863 A1	01-09-1994
			US	5761834 A	09-06-1998
US 4793078	A	27-12-1988	DE	3713786 A1	05-11-1987
			DE	8705983 U1	10-09-1987
			FR	2597728 A1	30-10-1987
			GB	2189372 A , B	28-10-1987
US 2389032	A	13-11-1945	NONE		
US 5452527	A	26-09-1995	NONE		